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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,571	12/05/2003	Marie Anderson	ASZD-P01-007	8775
44992	7590	12/29/2005	EXAMINER	
ASTRAZENECA R&D BOSTON 35 GATEHOUSE DRIVE WALTHAM, MA 02451-1215			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 12/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/729,571	Applicant(s) ANDERSON ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1-47 are pending in the application.

[3] Applicant's preliminary amendment to the specification, filed on 6/15/2004, is acknowledged.

[4] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, and an amendment directing entry of the substitute sequence listing, all filed on 9/24/2004, is acknowledged.

[5] Receipt of an information disclosure statement, filed on 10/20/2004, is acknowledged.

Election/Restrictions

[6] Claims 1, 3, and 5-6 link(s) inventions I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 3, and 5-6.

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[7] Claims 28, 30, 32, 34, and 40 link inventions VII-XXII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 28, 30, 32, 34, and 40.

[8] Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

[9] Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 7-11, drawn to a crystal of *H. pylori* Murl complexed with an inhibitor, classified in class 530, subclass 350.
- II. Claims 12-15, drawn to a crystal of *E. coli* Murl complexed with an inhibitor, classified in class 530, subclass 350.
- III. Claims 16-19, drawn to a crystal of *E. faecalis* Murl complexed with an inhibitor, classified in class 530, subclass 350.

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- IV. Claims 20-23, drawn to a crystal of *E. faecium* Murl complexed with an inhibitor, classified in class 530, subclass 350.
- V. Claims 24-27, drawn to a crystal of *S. aureus* Murl complexed with an inhibitor, classified in class 530, subclass 350.
- VI. Claims 2 and 4, drawn to a crystal of Murl complexed with an inhibitor and a substrate, classified in class 530, subclass 350.
- VII. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 4, classified in class 702, subclass 27.
- VIII. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 5, classified in class 702, subclass 27.
- IX. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a

compound using the relative structural coordinates of Figure 6, classified in class 702, subclass 27.

- X. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 7, classified in class 702, subclass 27.
- XI. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 8, classified in class 702, subclass 27.
- XII. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 9, classified in class 702, subclass 27.
- XIII. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted

method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 10, classified in class 702, subclass 27.

- XIV. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 11, classified in class 702, subclass 27.
- XV. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 12, classified in class 702, subclass 27.
- XVI. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 13, classified in class 702, subclass 27.

- XVII. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 14, classified in class 702, subclass 27.
- XVIII. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 15, classified in class 702, subclass 27.
- XIX. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 16, classified in class 702, subclass 27.
- XX. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a

compound using the relative structural coordinates of Figure 17, classified in class 702, subclass 27.

- XXI. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 18, classified in class 702, subclass 27.
- XXII. Claims 29, 31, 33, and 35, drawn to a computer-assisted method of identifying an agent that is an inhibitor of Murl, a computer-assisted method for designing an inhibitor of Murl activity, a method of identifying a molecule that binds to Murl, and a method for structure-based design of a compound using the relative structural coordinates of Figure 19, classified in class 702, subclass 27.
- XXIII. Claims 36-40, drawn to a method of assessing the *in vitro* binding of a Murl inhibitor, classified in class 435, subclass 7.1.
- XXIV. Claims 41 and 43-44, drawn to methods for conducting a pharmaceutical business, classified in class 514, subclass 789.
- XXV. Claim 42, drawn to methods for conducting a life science business, classified in class 514, subclass 789.
- XXVI. Claims 45-46, drawn to a method for treating a bacterial infection, classified in class 514, subclass 789.

XXVII. Claim 47, drawn to a pharmaceutical package comprising a composition of a Murl inhibitor, classified in class 514, subclass 789.

[10] The inventions are distinct, each from the other because:

[11] The crystals of Groups I-VI are distinct by virtue of their comprising structurally distinct polypeptides isolated from distinct sources and that each of the crystals has a distinct space group and unit cell dimensions. Further, none of the crystals of Groups I-VI would render any of the others obvious to one of ordinary skill in the art.

[12] The crystals of Groups I-VI are unrelated to the methods of Groups VII-XXVI as they are neither made nor used by the methods of Groups VII-XXVI.

[13] The crystals of Groups I-VI and the package of Group XXVII are unrelated, being capable of separate manufacture, use, and effect.

[14] The methods of Groups VII-XXVI are independent as they comprise different active method steps, utilize different products, and yield different results.

[15] The package of Group XXVII and the methods of Groups VII-XXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inhibitor of the package of Group XXVII can be used as an affinity reagent for purification of a Murl polypeptide.

[16] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and

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(B) There must be a serious burden on the examiner. As shown above, the inventions of Groups I-XXVII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. In view of the recited limitations of the claims of each invention, a separate patent and non-patent literature search and optionally sequence search for each Group is required. As such, co-examination of the inventions of Groups I-XXVII would require a serious burden on the examiner.

[17] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[18] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[19] The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

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include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116;

amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656